NHS
Cheshire and Merseyside

Vibegron for treating symptoms of overactive bladder syndrome (NICE TA999)

GREEN - non-specialist or specialist initiation and prescribing

Recommendations

The Cheshire and Merseyside Area Prescribing Group recommend vibegron for treating symptoms of overactive bladder syndrome, in accordance with NICE TA999.

Vibegron is recommended as an option for treating the symptoms of overactive bladder syndrome in adults. It is only recommended if antimuscarinic medicines are not suitable, do not work well enough or have unacceptable side effects.[1]

Prescribing information[2]

The recommended dose is 75 mg once daily.

Implementation notes

Vibegron may be initiated and prescribed for treating symptoms of overactive bladder syndrome within Primary and Secondary Care by a specialist or non-specialist.

Patient factors

Renal impairment - no dose adjustment is recommended for patients with mild, moderate, or severe renal impairment. Vibegron has not been studied in patients with end-stage renal disease (GFR <15 mL/min with or without haemodialysis) and is therefore not recommended in these patients.[2]

Hepatic impairment - no dose adjustment is recommended for patients with mild to moderate hepatic impairment (Child-Pugh A and B). Vibegron has not been studied in patients with severe hepatic impairment (Child-Pugh C) and is therefore not recommended in this patient population. [2]

Childbearing potential - those of childbearing potential must use contraception whilst taking vibegron.[2] Patients of childbearing potential who are planning to have a baby should not take vibegron. It is not known how vibegron will affect the foetus.[3]

Pregnancy - there are no or limited amount of data from the use of vibegron in pregnancy. Studies in animals have shown reproductive toxicity. Vibegron is not recommended during pregnancy. When pregnancy is planned or diagnosed, treatment with vibegron should be stopped and, if appropriate, alternative therapy should be started. [2]

Breast feeding - it is unknown whether vibegron/metabolites are excreted in human milk. A risk to newborns or infants cannot be excluded. Vibegron should not be used during breast-feeding.[2]

Safety[2]

Urinary retention - urinary retention has been reported in patients taking vibegron. The risk of urinary retention may be increased in patients with bladder outlet obstruction and also in patients taking muscarinic antagonist medicinal product concomitantly with vibegron treatment.

Signs and symptoms of urinary retention should be monitored before and during the treatment with vibegron, particularly in patients with clinically significant bladder outlet obstruction, in patients with conditions predisposing for bladder outlet obstruction, and in patients taking muscarinic antagonist medicinal product concomitantly with vibegron.

Vibegron should be discontinued in patients who develop urinary retention.

Adverse effects - The most frequently reported adverse reactions include urinary tract infection (6.6%), headache (5.0%), diarrhoea (3.1%) and nausea (3.0%).

Interactions - A single dose of 100 mg vibegron increased Cmax and AUC by 21% and 11%, respectively, of the P-gp substrate digoxin in healthy volunteers. Serum digoxin concentrations should be monitored and used for titration of the digoxin dose to obtain the desired clinical effect.

Refer to product SPC for full safety information.

Cost

Vibegron 75mg tablets - the NHS list price is £26.68 per 30-tablet pack (excluding VAT).[4] The annual treatment cost per patient is £325.
Mirabegron 25mg M/R tablets and 50mg M/R tablets - the NHS list price is £29.00 per 30-tablet pack (excluding VAT).[4] The annual treatment cost per patient is £353.

Effectiveness

Vibegron is a selective and potent human beta-3 adrenergic receptor agonist over β1-AR and β2-AR. Activation of the beta-3 adrenergic receptor located in the bladder detrusor muscle increases bladder capacity by relaxing the detrusor smooth muscle during bladder filling.[2]

The focus of results is placed on the pivotal Phase 3 EMPOWUR study and its extension. The EMPOWUR trial reported statistical superiority over placebo at 12 weeks in the coprimary endpoints of daily micturitions (-0.5, 95% CI -0.8 to -0.2, p< 0.001) and episodes of urinary incontience -0.6 (95% CI -0.9 to -0.3, p<0.0001). Vibegron was numerically, but not statistically, superior to tolterodine. The benefits of vibegron were observed after 2 weeks and persisted for at least 52 weeks. Vibegron was statistically superior compared with placebo in terms of the secondary outcome of urgency episodes, total incontinence episodes, and volume voided. Vibegron was non-statistically numerically superior compared with tolterodine in these outcomes. Vibegron significantly improved health-related quality of life compared with placebo when measured using the overactive bladder syndrome questionnaire and patient global impression instrument after 12 weeks of treatment.[5]

The EMPOWUR-EXT study reported continued efficacy against overactive bladder symptoms up to at least 52 weeks. Forty one percent of patients treated with vibegron had zero incontinence episodes over seven days at week 52 as evidenced by a 100% reduction in average daily number of urinary urge incontinence (UUI) episodes.[5]

References

1. National Institute for Health and Care Excellence. Technology Appraisal 999; Vibegron for treating symptoms of overactive bladder syndrome, 04 September 2024. Accessed 11 September 2024.
2. Pierre Fabre Limited. Summary of Product Characteristics; Obgemsa 75 mg film-coated tablets, 17 July 2024. Accessed 11 September 2024.
3. Pierre Fabre Limited. Patient information leaflet; Obgemsa 75 mg film-coated tablets, May 2024. Accessed 25 September 2024.
4. NHS Business Services Authority. dm+d browser (nhsbsa.nhs.uk). Accessed 05 August 2024.
5. National Institute for Health and Care Excellence. Technology Appraisal 999; Cost Comparison Appraisal. Vibegron for treating symtpms of overactive bladder [ID6300]. Committee Papers, 04 September 2024. Accessed 11 September 2024.

Patients who are not eligible for treatment under this policy may still be considered for treatment on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. Follow the locally defined process.